

Clinical Trial Protocol Cover Sheet

Study Title:

Impact of Holotropic Breathwork on Nursing Student Mental Health

Principal Investigator:

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College of Nursing

Study Sponsor:

Investigator-Initiated Study

ClinicalTrials.gov Identifier:

NCT07106554

Protocol Version/Date:

Version 1.0 – August 14, 2025

Study Phase:

Not Applicable (Behavioral Intervention Study)

Study Type:

Interventional (Behavioral)

Study Design:

Prospective, interventional study evaluating the psychological and experiential effects of a structured holotropic breathwork intervention among nursing students. Participants will complete baseline, immediate post-session, and longitudinal follow-up assessments.

Estimated Enrollment:

Up to 72 participants

Study Population:

Graduate nursing students recruited via email invitation from the Principal Investigator.

Study Sites:

University of Nebraska Medical Center, College of Nursing

Lincoln, Nebraska, United States

Brief Summary:

This study evaluates the psychological, emotional, and experiential outcomes associated with participation in structured holotropic breathwork sessions. Participants will complete

baseline surveys assessing mood, anxiety, functioning, and purpose in life prior to participation. They will then engage in a facilitated holotropic breathwork session conducted by certified facilitators following established safety protocols. Post-experience and longitudinal follow-up assessments at one, three, and six months will measure psychological insight, emotional processing, mood, anxiety, and functioning. Safety monitoring includes structured review of depression and suicidality screening measures with defined clinical follow-up procedures.

Primary Objectives:

- To evaluate changes in psychological insight, emotional processing, and subjective experience following holotropic breathwork.
- To assess changes in mood, anxiety, interpersonal functioning, and purpose in life over time.
- To evaluate the safety and tolerability of structured holotropic breathwork in this population.

Intervention:

Participants will attend a structured holotropic breathwork workshop facilitated by certified practitioners and trained assistants. The session includes preparation, guided breathing with music support, integration activities, and post-session processing.

Outcome Measures:

- Mystical Experiences Questionnaire
- Challenging Experiences Questionnaire
- Emotional Breakthrough Inventory
- Psychological Insight Scale
- PHQ-9
- GAD-7
- Self and Interpersonal Functioning Scale
- Purpose in Life Test–Short Form

Study Duration:

Each participant will be followed for approximately 6 months following the intervention.

Safety Monitoring:

Depression and suicidality screening responses will be reviewed promptly. Participants with elevated risk scores will receive direct clinical follow-up and referral for evaluation as indicated.

Regulatory/Ethics:

This study will be conducted in accordance with applicable federal regulations, institutional policies, and ethical standards for human subjects research. Institutional Review Board (IRB) approval has been obtained prior to participant enrollment.

Protocol:

The PI will send an e-mail about the opportunity to participate in this study. Interested students will be instructed to contact the PI by e-mail.

The PI will send a follow-up e-mail to anyone who expresses interest. This e-mail will include links to two YouTube videos

(<https://www.youtube.com/watch?v=prfll4C1zw0&t=423s>; <https://www.youtube.com/watch?v=2TyGgTqyahk>). Watching these videos will help give potential participants a better understanding of holotropic breathwork.

Individuals who are still interested in participating after watching the two videos will be asked to send another e-mail to the PI.

The PI will schedule meetings either in-person or over Zoom to complete the informed consent process. He will describe the process of Holotropic Breathwork (HB) and the procedures for the study. After answering any questions and ensuring understanding, potential participants will be given the opportunity to sign the informed consent form either on paper or through DocuSign.

One week before the breathwork is to take place, the PI will e-mail participants a REDCap survey. Baseline surveys will include demographics (sex, age, program of study), the Patient Health Questionnaire-9, the General Anxiety Disorder-7, the Self and Interpersonal Functioning Scale, and the Purpose in Life Test-Short Form.

Participants will be instructed to arrive at the College of Nursing Lincoln campus the morning of the breathwork. All people of child-bearing potential will be administered a CLIA-waived urine pregnancy test. Any individuals with a positive test will be withdrawn from the study at that time. In addition, individuals may be withdrawn from the study if they state they no longer want to participate. However, a facilitator will have an individual discussion with them before they leave to make sure they are not experiencing psychological distress for which they need support. The breathing exercises used in HB rarely elicit asthma attacks but participants with asthma will be asked to bring an inhaler as a precautionary measure. If a participant experiences an asthma attack which is resolved by the inhaler and they would like to remain with the group, they will be allowed to continue their participation. In the unlikely event that any participant experiences a medical event requiring outside treatment, they will be withdrawn from the study.

Up to 36 participants may take part in each of the two breathwork sessions for a total of up to 72 participants.

The session will start with an opening circle in which the participants will be asked to introduce themselves and say anything they would like about what brought them to the

breathwork.

Holotropic breathwork rules state that each group session must be run by at least two fully certified facilitators. Jeffrey Warren and Dory Perry are certified. "Apprentices" are individuals in the Grof Transpersonal Training program who have completed all of the requirements except the closing certification. They work under the close supervision of facilitators as a requirement to prepare for their closing certification. Samuel Dye and Sarah Hart will work as apprentices in these sessions.

The facilitators will then give a 60-minute presentation. All participants will be asked to agree to confidentiality, not leaving the workshop without meeting with the facilitators and PI, and not causing harm to self, others, or property. The facilitators will then explain the role of the sitter and breather.

The facilitators will give a 60-minute introduction presentation. During this time, they will discuss the concept of the inner healer, or the self's ability to heal itself similar to the body healing itself from a cut. They will then discuss hylotropic (ordinary consciousness oriented towards tangible realities) and holotropic (non-ordinary states of consciousness oriented towards intangible reality) states. A history of non-ordinary states of human consciousness will be discussed including religious traditions, meditation, psychedelic plants, fasting, dancing, near death experiences, and breathing.

They will then discuss the history of how Stanislav Grof developed holotropic breathwork. Helpful tips for experiencing non-ordinary states of consciousness will be discussed including letting go, trusting the inner wisdom, and obtaining information. Grof's cartography of the psyche will be reviewed including biographical experiences, perinatal experiences, and transpersonal experiences. Next, the COEX, or system of emotionally charged memories and how they may arise during breathwork will be discussed. The possibility of yogic sleep states will be reviewed.

Working through challenging experiences will also be discussed including persistent thoughts and projection.

More practical aspects of the breathwork will be reviewed including signals for requesting water, a tissue, assistance to the restroom, and other anticipated needs will be discussed. Activities participants may engage in once they are finished with the breathwork will be reviewed. Option may include writing or making art (commonly in the form of a mandala).

Lastly, they will review the process of concluding the breathwork session which includes meeting with a facilitator to make sure they are psychologically ready to move on to another activity.

Participants will select a partner with whom they feel most comfortable. This process has worked in thousands of breathwork events across many countries. However, if participants

are unable to make acceptable matches, the facilitators will help with this process. If there is an odd number of participants, breathwork can also be completed with two breathers and one sitter for one session and one breather and two sitters in the next. The facilitators will be available to help at any time.

The session starts with a guided relaxation exercise. The breather lies on a mat on the floor. Most participants use eyeshades to help reduce external distractions and focus on their internal experiences.

After the guided relaxation exercise, participants are given instructions to gradually start breathing more deeply and to shorten the duration between breaths. Participants may breathe as deeply and rapidly as feels right for them. Most participants will breathe more deeply and rapidly until they start to notice a mental shift at which time they will resume normal breathing. They will also be told they can return to the deep and rapid breathing as often as they feel the need during the breathwork.

A set of purposefully selected music is played over a two to three-hour period to help support the participants' experience. Individuals show significant variability in their response to HB sessions. Some participants lay still and quiet, while others display significant movement and may make vocalizations according to their internal experience. The role of the sitter is to hold space and provide whatever support the breather may need. They will often get tissues if the participant is crying, hand a bottle of water, and walk them to the restroom as the breather may be slightly unsteady. Critically, the sitter avoids interfering in the breathers experience unless help is specifically requested. Hand signals for tissues, water, and restroom are often established before the session to facilitate communication.

Facilitators manage the music and help ensure everyone in the room remains safe. At least two facilitators and often apprentices (people training to be facilitators) are present in a ratio of approximately 1:5 for breathers who need more intensive assistance. For example, a breather may encounter blocked energy or be experiencing a re-birthing process.

The support provided during the breathwork varies greatly depending on an individual's needs. Some participants may say they are unsure what to do next in which case the facilitator may simply suggest they return to the more intense breathing or provide reassurance that they are doing well. In other cases, a participant may request to hold their sitter or facilitator's hand. Alternatively, a participant may express a desire to put pressure against a wall or a sitter/facilitator (similar to stretching or isometric exercises). Great care is taken to only provide resistance. In this way, the participant has full control of the intensity and duration of the movement.

All interventions take place only at the specific and explicit request of the participant. The

sitter/facilitators do not try to interpret what they see or guess what the participant needs. Rare situations in which a participant will be prevented from acting out include harming themselves or someone else, property, or interactions which could be construed as sexual in nature.

Facilitators have specific training and experience to safely assist participants through these processes. In addition, facilitators sit with a breather if their sitter needs to take a short break so that no breather is ever left alone.

After the three-hour music playlist has ended, breathers gradually return to normal consciousness. The facilitators have a short individual discussion with each breather. This allows the facilitator to assess the mental state of the individual and determine if they need any support. The breather may need a chance to describe their experience or may need more time. The processing may take place in the room where the breathwork was completed if this is most comfortable for the participant. A facilitator may also take them to another room for greater privacy if the participant desires. The facilitator will remain with the participant until they feel "complete" for the time being and believe they are ready to rejoin the larger group.

After the first session, a light lunch will be served.

After the lunch, the same breathwork procedure will be repeated with the roles in the pair reversed (i.e. the first breather will become the sitter and vice-versa).

Once all participants in the second group have finished their breathwork experience, the facilitators will give another 60-minute presentation. The post-session will focus on integration. Formal and informal integration will be defined with examples. The importance of integration will then be discussed. Self-care will be discussed including relaxation, food, trusted people, art, dance, music meditation, spiritual practices, journaling, and therapy. The facilitators will discuss the importance of knowing what and with whom to share the experience. There will then be a discussion of managing outside stimulation to facilitate integration. Lastly, participants will be advised to delay making important decisions on life changes until participants have time to consider the decision and possibly seek feedback from trusted individuals.

A closing circle will then be held in which participants can say whatever they would like about their experience. Individuals speak only about their own experience and no feedback is given.

Anyone who feels that they need more help to process their experience can meet individually with an experienced facilitator after the rest of the participants have been dismissed.

Before they leave the campus, participants will be asked to complete the post-experience survey which include the Mystical Experiences Questionnaire, The Challenging Experiences Questionnaire, the Emotional Breakthrough Inventory, and the Psychological Insight Scale.

One, three, and six months after the HB, the PI will e-mail a final REDCap link to participants. This survey will also include the Psychological Insight Scale, the Patient Health Questionnaire-9, the General Anxiety Disorder-7, the Self and Interpersonal Functioning Scale, and the Purpose in Life Test-Short Form.

The PI will set REDCap to notify him each time a survey is completed. He will review the results of each PHQ-9 submitted within one hour if it is received between 8am and 10pm and the next morning by 9am if it is received overnight. If the PI is unavailable, Dr Terri Mathews (psychologist and psychiatric nurse practitioner) will assume the role of reviewing REDCap responses and taking appropriate action.

If the total score was greater than 14 and the participant responded affirmative to question 9, he will contact the participant by phone and e-mail to arrange for emergency evaluation. If no response is received by phone or e-mail within 30 minutes, he will call local authorities to arrange for a welfare check.

If the total score was greater than 14 and the participant responded negatively to question 9, he will contact the participant by phone and e-mail to arrange a mental health consultation.

If the total score was less than 14 and the participant responded affirmative to question 9, he (as a psychiatric nurse practitioner) will conduct further assessment with the participant and refer as necessary.

If a participant is unsteady at the end of the day, a ride home will be arranged for them by Lyft or Uber. If needed, a ride (Lyft or Uber) will also be arranged for them back to get their car the next day.